**UNITED STATES**
**SECURITIES AND EXCHANGE COMMISSION**
**Washington, D.C. 20549**

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**FORM 6-K**

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**REPORT OF FOREIGN PRIVATE ISSUER**
**PURSUANT TO RULE 13a-16 OR 15d-16**
**UNDER THE SECURITIES EXCHANGE ACT OF 1934**

**September 2022**

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**Commission File Number:** 001-38723

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**Tiziana Life Sciences LTD**
(Exact Name of Registrant as Specified in Its Charter)

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**9th Floor**
**107 Cheapside**
**London**
**EC2V 6DN**
(Address of registrant's principal executive office)

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Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

**INFORMATION CONTAINED IN THIS REPORT ON FORM 6-K**

On September 20, 2022, Tiziana Life Sciences LTD (the "Company") issued a news service announcing continued clinical improvements in the second patient with Secondary Progressive Multiple Sclerosis (SPMS) after six months of dosing with intranasal foralumab.

The Announcement is furnished herewith as Exhibit 99.1 to this Report on Form 6-K. The information in the attached Exhibit 99.1 is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing made by the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, except as otherwise set forth herein or as shall be expressly set forth by specific reference in such a filing.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**TIZIANA LIFE SCIENCES LTD**

Date: September 20, 2022

By: /s/ Keeren Shah
Name: Keeren Shah
Title: Finance Director

**EXHIBIT INDEX**

| Exhibit No. | Description |
| --- | --- |
| 99.1 | News Service Announcement, dated September 20, 2022 |

**Exhibit 99.1**

**Tiziana Life Sciences Announces Continued Clinical Improvements in the Second Patient with Secondary Progressive Multiple Sclerosis (SPMS) After Six Months of Dosing with Intranasal Foralumab**

- **The second Expanded Access patient (EA2) demonstrated improved walking as measured by gait stability and endurance**
- **The patient showed clinically significant improvement in the Expanded Disability Status Scale (EDSS).**
- **The 6-month PET imaging will occur in Q4 2022 to confirm simultaneous improvements in microglial activation**

NEW YORK, Sept. 20, 2022 - Tiziana Life Sciences Ltd. (Nasdaq: TLSA) ("Tiziana" or the "Company"), a biotechnology company developing breakthrough immunomodulation therapies via novel routes of drug delivery, today announced that the second patient ("EA2") with non-active secondary progressive multiple sclerosis (SPMS) receiving intranasal foralumab has shown additional clinical improvements as measured by the Expanded Disability Status Scale (EDSS), a standard clinical assessment.

On September 12th, 2022, this patient had walked 100 meters without a cane or need for rest. Prior to this, on June 8, 2022, the patient required a cane to walk 100 meters. This corresponds with a clinically meaningful improvement in the EDSS score of 0.5. The patient's pyramidal score remained stable and did not worsen over time. This patient has received a total of 10.5 treatment cycles of foralumab to date.

"Coupled with our PET imaging data demonstrating inhibition of microglial activation, I am truly excited and encouraged by the clinical benefits shown so far for the first two expanded access patients receiving intranasal foralumab for SPMS", commented Gabriele Cerrone, Executive Chairman and interim Chief Executive Officer of Tiziana. "This program is a top priority for us, and we expect to enroll four additional patients with SPMS at Brigham and Women's Hospital (BWH) in Q4 2022."

Howard L. Weiner, M.D., Co-Director of the Ann Romney Center for Neurologic Diseases at BWH and Chairman of Tiziana's Scientific Advisory Board, stated, "I am pleased, but not surprised to see additional clinical improvement in the second patient. SPMS represents an advanced stage of multiple sclerosis with few treatment options and creates a severe burden on patients."

Dr. Tanuja Chitnis, M.D., Professor of Neurology and the Principal investigator of the clinical study at BWH said, "Patients with non-active SPMS normally do not improve over a six-month time course. I am very encouraged by these results and look forward to seeing this patient's PET imaging to determine if there is a continued reduction in microglial activation to correlate with the improvement we are observing in the patient's clinical exam."

**About Foralumab**

Foralumab (formerly NI-0401), the only entirely human anti-CD3 mAb, has shown reduced release of cytokines after IV administration in healthy volunteers and in patients with Crohn's disease. In a humanized mouse model (NOD/SCID IL2γc-/-), it was shown that while targeting the T-cell receptor, orally administered foralumab modulates immune responses of the T-cells and enhances regulatory T-cells (Tregs), thereby providing therapeutic benefit in treating inflammatory and autoimmune diseases without the occurrence of potential adverse events usually associated with parenteral mAb therapy. Once a day treatment for 10 consecutive days with intranasal foralumab was both well tolerated and produced clinical responses in COVID-19 patients. Based on these studies, the intranasal and oral administration of Foralumab offers the potential to become a well-tolerated immunotherapy for autoimmune and inflammatory diseases by the induction of Tregs.

**About Tiziana Life Sciences**

Tiziana Life Sciences is a clinical-stage biopharmaceutical company developing breakthrough therapies using transformational drug delivery technologies to enable alternative routes of immunotherapy. Tiziana's innovative nasal, oral and inhalation approaches in development have the potential to provide an improvement in efficacy as well as safety and tolerability compared to intravenous (IV) delivery. Tiziana's two lead candidates, intranasal foralumab, the only fully human anti-CD3 mAb, and milciclib, a pan-CDK inhibitor, have both demonstrated a favorable safety profile and clinical response in patients in studies to date. Tiziana's technology for alternative routes of immunotherapy has been patented with several applications pending and is expected to allow for broad pipeline applications.

For further inquiries:

**Tiziana Life Sciences Ltd**

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